510(k) Summary

JUN 1 1 2007

The assigned 510(k) number is: K070453/S1

This summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

1. Submitter name, address, contact	Olympus Life and Material Science Europa GmbH Lismeehan, O'Callaghan's Mills Co. Clare, Ireland	
	U.S. Telephone: U.S. Fax: Telephone:	469-230-0959 972-317-7861 011-353-65-683-1100
	Contact Person:	Stephanie G. Schwartz
	Date Prepared:	April 25, 2007
2. Device name	Proprietary Name:	Olympus D-Dimer Reagent (OSR6x135) Olympus D-Dimer Calibrator (ODR3033) Olympus D-Dimer Control (ODC0029)
	Common Name:	D-Dimer Reagent, Calibrator and Control
	Classification Name:	Fibrinogen/fibrin degradation products assay
3. Predicate device	Reagent: Calibrator Control	Roche Tina-Quant® D-Dimer Roche D-Dimer Calibrator Roche D-Dimer Control I/II
		Submitted (K030740 & K002706)
4. Device description	In this Olympus procedure, the decrease in light intensity transmitted (increase in absorbance) through particles suspended in solution is as a result of complexes formed during the immunological reaction between the D-Dimer of the patient serum and the anti-human D-Dimer antibodies coated on the latex particles	
5. Intended use	System reagent for the quantitative determination of D-Dimer in human plasma on Olympus analyzers The Olympus D-Dimer Calibrator is designed to provide suitable calibration levels for Olympus analyzers employing the immuno-turbidimetric assays for D-Dimer determinations The Olympus D-Dimer Control is a lyophilized human control. These assayed controls are designed to monitor the accuracy and precision of the quantitative Olympus D-Dimer reagents.	

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6. The following Tables compare the new Olympus D-Dimer Test System with the Roche Tina-Quant® D-Dimer Test System.

Similarities		
Item	Olympus D-Dimer Test System	Predicate System
Intended Use	Reagent for the quantitative determination of D-Dimer in human plasma	Assay for quantitative determination of D-Dimer in human plasma
Traceability	Another Commercially available assay	Same
Measurement	Quantitative	Same
Specimen Type	Citrate and Lithium Heparin Plasma	Same
Assay Methodology	Latex enhanced Immunoturbidimetric	Same
Antibody	Monoclonal anti human D-Dimer mouse antibodies	Same
Solid Phase	Latex Particle	Same
Reagent storage form	Liquid On –board storage	Same
Reagent Handling	R1 Ready for use R2: Mix before placing on instrument and at weekly intervals thereafter	Same
Calibrator and Control Constituents	Single	Same
Calibrator and Control Material	Human Origin	Same
Calibrator Storage form	Calibrator 1 : Liquid ready to use Calibrator 2 : Lyophilized Powder	Same
Calibration	6 points	Same
Quality Controls	2 Levels	Same
Control Storage Form	Lyophilized Powder	Same
Expected Values	< 0.5 µg FEU/mL	Same

Differences		
Item	Olympus D-Dimer Test System	Predicate System
Instrument required	Olympus AU400/400e, 600/640/640e and 2700/5400	Roche/Hitachi analyzers. Calibrator and control can also be used with Roche Cobas Integra analyzers.
Intended Use	System reagent for the quantitative determination of D-Dimer in human plasma on OLYMPUS analyzers	Immunoturbidimetric assay for the in vitro quantitative determination of fibrin degradation products including D-Dimer and X-oligomers in human plasma on Roche automated clinical chemistry analyzers.
Traceability/Standardization	Traceable to an in-house Master Calibrator and aligned with another commercially available test system	The Roche Tina-Quant® D-Dimer method was calibrated against the Asserachrom D-Dimer method
Reagent On Board Stability	30 days on board	28 Days on board
Calibrator Open Vial Stability	• 1 day @ 15 - 25°C • 28 days @ 2 - 8°C • 30 days @ -20°C	1 day @ 15 -25°C
Control Open vial Stability	• 1 day @ 15 - 25°C • 28 days @ 2 - 8°C • 30 days @ -20°C	• 1 day @ 15 - 25°C • 14 days @ 2 - 8°C
Calibration Stability	30 days	Not Specified

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Performance Characteristics		
Item	Olympus D-Dimer Test System	Predicate System
Precision	AU400/400e Sample Total CV% 1 9.44 2 7.99 3 2.48 AU600/640/640e Sample Total CV% 1 9.14 2 7.95 3 3.02 AU2700/5400 Sample Total CV% 1 8.17 2 4.44 3 2.52	Sample Total CV% 1 6.5 2 8.3 3 3.2
Assay Range	0.15 - 8.00 µg FEU/mL	0.15 - 9.0 µg FEU/mL
Analytical Sensitivity	0.08 µg FEU/mL	0.04 µg FEU/mL
Method Comparison (Linear Regression)	Intercept 0.079 Slope 1.010 R^2 0.996 Range 0.28-7.53 µg FEU/mL	Intercept 0.06 Slope 0.87 R^2 0.755 Range 0.08-4.55 µg FEU/mL
Interfering Substances	AU400/400e, 600/640/640e & 2700/5400 Interference less than 10% • Bilirubin: up to 40 mg/dL Bilirubin • Hemolysis: up to 500 mg/dL Hemolysate • Rheumatoid Factor: up to 100IU/mL • Heparin: up to 1.5 IU/mL AU400/400e & 600/640/640e Interference less than 10% • Lipemia: up to 1000 mg/dL Intralipid 2700/5400 Interference less than 10% • Lipemia: up to 700 mg/dL Intralipid	Roche Analyzers within ± 10% of initial value • Bilirubin up to 20 mg/dL Bilirubin • Hemolysis: up to 500 mg/dL Hemoglobin • Rheumatoid Factor: < 100 IU/mL • Heparin: < 1.5 IU/mL • Lipemia: up to 1500 mg/dL Triglyceride Concentration

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 11 2007

Stephanie Schwartz
Olympus Life & Material Science Europa GMBH
c/o Olympus America, Inc.
3131 West Royal Lane
Irving, Texas 75063

Re: k070453
Trade/Device Name: Olympus D-Dimer Reagent, Olympus D-Dimer Calibrator, Olympus D-Dimer Control
Regulation Number: 21 CFR 864.7320
Regulation Name: Fibrinogen/fibrin degradation products assay
Regulatory Class: Class II
Product Code: GHH
Dated: April 25, 2007
Received: April 30, 2007

Dear Ms. Schwartz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150, or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Robert L. Becker, Jr., MD, PhD
Director
Division of Immunology and Hematology
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070453

Device Name: Olympus D-Dimer Test System

Indications for Use:

System reagent for the quantitative determination of D-Dimer in human plasma on OLYMPUS analyzers.

Aid in detecting the presence and degree of intravascular coagulation and fibrinolysis, and in monitoring therapy for disseminated intravascular coagulation.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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